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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,760	07/09/2003	Harry V. Gelboin	015280-389200US	2288

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,760	GELBOIN ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-73 are pending.

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. The following is noted:

Claims 1, 13, 27, 28, 41, 53, 67, 72 and 73 are directed to a "binding agent" or to a method of detection using said binding agent, wherein said binding agent competes with various monoclonal antibodies for specific binding to a particular antigen. For examination purposes, the "binding agent" of the instant claims will be restricted to the extent that it reads on "antibodies".

It is noted that the instant specification discloses on page 18, lines 18-23 various "non-antibody binding agents" such as other polypeptides, polysaccharides, phospholipids, steroids, aromatic compounds. These non-antibody binding agents do not share *a substantial structural feature essential to a common utility.* These structurally distinct agents are subject to restriction, rather than election of species (as per M.P.E.P. 803.02), and if they are introduced into the claims they will be subject to further restriction.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-12 are drawn to a binding agent as it reads on an antibody that competes with **MAb 292-2-3** for binding to a particular antigen, and to **cell lines** that produce monoclonal antibody binding agents, classified in Class 530 subclass 387.1; Class 435, subclass 326.

II. Claims 13-26 are drawn to a binding agent as it reads on an antibody that competes with **MAb 763-15-5** for binding to a particular antigen, and to **cell lines** that produce monoclonal antibody binding agents, classified in Class 530, subclass 388.1; Class 435, subclass 332.

III. Claim 27 drawn to a binding agent as it reads on an antibody that competes with **MAb 763-15-20** for binding to a particular antigen, classified in Class 530, subclass 388.2.

IV. Claims 28-40 are drawn to a binding agent as it reads on an antibody that competes with a monoclonal antibody selected from the group consisting of **MAb 5-1-5 and MAb 281-1-1** for binding to a particular antigen, and to **cell lines** that produce monoclonal antibody binding agents, classified in Class 530, subclass 388.23; Class 435, subclass 336.

V. Claims 41-52 are drawn to a binding agent as it reads on an antibody that competes with **MAb 592-2-5** for binding to a particular antigen, and to **cell lines** that produce monoclonal antibody binding agents, classified in Class 530, subclass 388.23; Class 435, subclass 326.

VI. Claims 53-66 are drawn to a binding agent as it reads on an antibody that competes with **MAb 5-7-5** for binding to a particular antigen, and to **cell lines** that produce monoclonal antibody binding agents, classified in Class 530, subclass 388.2; Class 435, subclass 332.

VII. Claims 67-71 are drawn to a method of **determining/detecting cytochrome P450 2C9*2 metabolism** of a compound using the binding agent of claim 1, classified in Class 435, subclass 4.

VIII. Claims 72-73 are drawn to a method of **detecting cytochrome P450 2C9*2** in a sample or in a sample taken from an individual using the binding agent of claim 1, classified in Class 435, subclass 7.1.

5. Groups I-VI are different products. The antibody binding agents differ in their epitopic specificities, which, in turn bind to distinct structures. Therefore, both the antibodies and their targets have different physiochemical structures and properties. Moreover, they require non-coextensive searches in the scientific literature. Thus, these products are patentably distinct, and searching these inventions would impose an undue burden.

6. Groups I and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the product antibody binding agent can be used for affinity purification in addition to methods of detecting the presence of cytochrome P450 2C9*2 or detecting the ability of cytochrome P450 2C9*2 to metabolize a compound.

7. Groups VII and VIII are different methods, which differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these invention together.

8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary Skelding, Ph.D.
Patent Examiner
March 13, 2006

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
3/14/06